

510(K) Summary

CarboFix Orthopedics Ltd.

Piccolo Composite™ Nailing System – Tibia & Femur

Applicant Name

CarboFix Orthopedics Ltd.

11 Ha'hoshlim St., Herzeliya 46724, Israel

Contact Person

Yael Rubin

CarboFix Orthopedics Ltd.

11 Ha'hoshlim St., Herzliya 46724, Israel

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Date Prepared

April 2011

Trade/Proprietary Name

Piccolo Composite Nailing System

Common Name

Intramedullary Nailing System

Classification Name

Rod, Fixation, Intramedullary and Accessories (21 CFR §888.3020; Product Code HSB)

Predicate Devices

- Piccolo Composite™ Nailing System (CarboFix Orthopedics Ltd.); K091425, K100497, K102369)
 - T2 Tibial Nail (Stryker (Howmedica Osteonics Corp.); K003018 and more)
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- T2 Femoral Nail (Stryker (Howmedica Osteonics Corp.); K010801 and more)
- UTN Solid Tibial Nail/CTN Cannulated Tibial Nail (Synthes; K914453, K962047)
- Expert R/AFN Retrograde/Antegrade Femoral Nail (Synthes; K033618)
- Fixion® Interlocking Intramedullary Nailing System (CarboFix Orthopedics Ltd.); K002783, K013449, K032588)
- M/DN® Intramedullary Fixation System (Zimmer; K965098)

Intended Use/Indications for Use

Piccolo Composite Tibial and Femoral Nails

Indications for the Piccolo Composite Tibial and Femoral Nails include simple fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Piccolo Composite Tibial and Femoral Nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

System Description

The Piccolo Composite Nailing System includes nails, screws and a set of instruments.

The Piccolo Composite Nail, indicated for treatment of the tibia and femur, is a cannulated, cylindrical rod, made of carbon fiber reinforced polymer. The tibial nail diameter ranges from 9 to 11 mm, with lengths in the range of 260 to 400 mm; the femoral nail diameter ranges from 10 to 12 mm, with lengths in the range of 160 to 420 mm. The nails provide for holes at the proximal and distal sections, designed for the insertion of titanium-alloy-made screws. The nail has a pointed distal end, and its proximal end incorporates a thread enabling connection of insertion/extraction instrumentation.

Substantial Equivalence

The Piccolo Composite Nailing System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

The Company performed static 4-point bending evaluation, static torsion evaluation, dynamic evaluation, and evaluation supporting MR Conditional labeling, demonstrating that the device is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

CarboFix Orthopedics Ltd.
% Ms. Yael Rubin
Director of Regulatory Affairs
Ha'hoshlim Street 11
46724 Herzeliya
Israel

MAY - 3 2011

Re: 'K111056

Trade/Device Name: Piccolo Composite™ Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 14, 2011
Received: April 18, 2011

Dear Ms. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

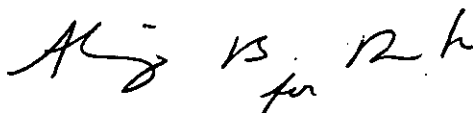
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson' with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K111056

Device Name: Piccolo Composite™ Nailing System

Indications for Use:

Piccolo Composite Tibial and Femoral Nails

Indications for the Piccolo Composite Tibial and Femoral Nails include simple fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Piccolo Composite Tibial and Femoral Nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

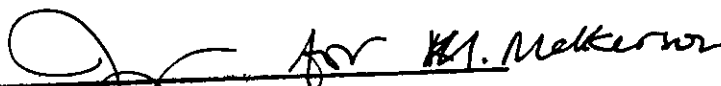
Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111056